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New York State Agricultural Experiment Station

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Dear Sir/Madam

As the North East Regional Laboratory Research Director of the Interregional Research Project No.4 (IR-4) I would like to make some comments on the Agency's proposed Electronic Record-Keeping Rule (CROMERRR).

The NE Region IR-4 Laboratories would suggest that the electronic record keeping be separated from the rest of the Rule and that the enforcement of the Rule be postponed until EPA's responsible offices have defined what system would be appropriate and how to implement it. Furthermore, the cost of this rule will be astronomical, and it will delay our research since the instruments are not equipped for electronic record keeping, and personnel is not trained for such systems.

What is this rule going to accomplish? Is the objective to deter fraud? How much data or records have been found to be fraudulent? CROMERRR is certainly not the most efficient and cost effective way to prevent falsification of data. With exorbitant costs and setback of research productivity this rule will do more harm than good.

Within IR-4 all research is done in compliance with GLP and all facilities have a Quality Assurance unit that reassure that the research fulfills the requirements of GLP and SOPs. In addition EPA audits are performed randomly.

If "raw" data are defined as the originals and kept as the paper printouts, data could still be collected from the various instrument computers but the electronic record-keeping rule would not apply. The results in the report would be reviewed and compared to the "raw" data printouts to assure that they reflect the original data and the final report could then be submitted electronically.

We are looking forward to the continued dialog regarding CROMERRR and are hoping that a final Rule will be established that will be adequate to all involved.

Respectfully submitted,

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